

QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY



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What are Occupational Standards (OS)?

- OS describe what individuals need to do, know and understand in order to carry out a particular job role or function
- OS are performance standards that individuals must achieve when carrying out functions in the workplace, together with specifications of the underpinning knowledge and understanding

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Introduction

Qualifications Pack - Quality Control Biologist

SECTOR: LIFE SCIENCES

SUB-SECTOR: BIO PHARMACEUTICAL

OCCUPATION: QUALITY

REFERENCE ID: LFS/Q2301

ALIGNED TO: NCO-2004/ NIL

A Quality Control Biologist is responsible for conducting qualitative and quantitative analysis to ensure specified quality of the manufactured bio pharmaceutical products

Brief Job Description: A Quality Control Biologist prepares and tests samples from all phases of the bio pharmaceutical product manufacturing process to ensure that the product quality meets standards. He/she prepares documents that report test results and is responsible for preserving workplace safety while handling hazardous materials. Also responsible for testing in-process/input raw material, packaging materials, in-process samples, finished products, process validation samples, product stability samples and cleaning validation samples, as well as vaccine-candidate test method development, optimization, verification and validation.

Personal Attributes: The individual should have good lab-work skills and thorough understanding of testing material, equipment and processes along with good knowledge of assays.

Job Details	Qualifications Pack Code	LFS/Q2301		
	Job Role	Quality Control Biologist		
	Credits(NSQF)	TBD	Version number	1.0
	Sector	Life Sciences	Drafted on	22/12/14
	Sub-sector	Bio Pharmaceutical	Last reviewed on	01/08/16
	Occupation	Quality	Next review date	01/08/19
	NSQC Clearance on	20/07/2015		

Job Role	Quality Control Biologist
Role Description	Responsible for conducting qualitative and quantitative analysis to ensure specified quality of the manufactured products
NSQF level	5
Minimum Educational Qualifications	B. Pharma / Graduation in Biotechnology/ B. Sc with Chemistry/ Biology/Microbiology/ Biochemistry as major subject (Preferable)
Maximum Educational Qualifications	M. Pharma/ M.Tech Chemical/Biotechnology/ M. Sc with Chemistry/ Biology/Microbiology/ Biochemistry as major subject (Preferable) Quality related certification
Training (Suggested but not mandatory)	On the job training
Minimum Job Entry Age	20 Years
Experience	0-2 years
Applicable National Occupational Standards (NOS)	<p>Compulsory:</p> <ol style="list-style-type: none"> LFS/N0338: Analyze bio-pharmaceuticals in lab while ensuring compliance with Good Manufacturing Practices(GMP) and Good Laboratory Practices (GLP) LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility LFS/N0302: Coordinate with Supervisors and colleagues within and outside the department LFS/N0103: Ensure cleanliness in the work area

	<p>5. LFS/N0314: Carry out reporting and documentation to meet quality standards</p> <p>6. LFS/N0320: Carry out quality checks in the quality control process</p>
	<p>Optional: N.A.</p>
Performance Criteria	As described in the relevant NOS units

Definitions

Keywords /Terms	Description
Core Skills/Generic Skills	Core Skills or Generic Skills are a group of skills that are key to learning and working in today's world. These skills are typically needed in any work environment. In the context of the NOS, these include communication related skills that are applicable to most job roles.
Description	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate NOS they are looking for.
Function	Function is an activity necessary for achieving the key purpose of the sector, occupation, or area of work, which can be carried out by a person or a group of persons. Functions are identified through functional analysis and form the basis of NOS.
Job role	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
Knowledge and Understanding	Knowledge and Understanding are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.
National Occupational Standards (NOS)	NOS are Occupational Standards which apply uniquely in the Indian context.
Occupation	Occupation is a set of job roles, which perform similar/related set of functions in an industry.
Organisational Context	Organisational Context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Performance Criteria	Performance Criteria are statements that together specify the standard of performance required when carrying out a task.
Qualifications Pack(QP)	Qualifications Pack comprises the set of NOS, together with the educational, training and other criteria required to perform a job role. A Qualifications Pack is assigned a unique qualification pack code.
Qualifications Pack Code	Qualifications Pack Code is a unique reference code that identifies a qualifications pack.
Scope	Scope is the set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on the quality of performance required.
Sector	Sector is a conglomeration of different business operations having similar businesses and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.

Sub-Sector	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
Sub-functions	Sub-functions are sub-activities essential to fulfil the achieving the objectives of the function.
Technical Knowledge	Technical Knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Unit Code	Unit Code is a unique identifier for an NOS unit, which can be denoted with an 'N'.
Unit Title	Unit Title gives a clear overall statement about what the incumbent should be able to do.
Vertical	Vertical may exist within a sub-sector representing different domain areas or the client industries served by the industry.
Keywords /Terms	Description
NOS	National Occupational Standard(s)
NSQF	National Skill Qualifications Framework
NCO-2004	National Classification of Occupations-2004
OS	Occupational Standard(s)
QP	Qualifications Pack
QC	Quality Control
SOP	Standard Operating Procedures
GMP	Good Manufacturing Practices
GLP	Good Laboratory Practices

LFS/N0338 : Analyse bio-pharmaceuticals in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

National Occupational Standards

Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Quality Control Biologist to perform bio analysis in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

LFS/N0338 : Analyse bio-pharmaceuticals in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

National Occupational Standard	Unit Code	LFS/N0338
	Unit Title (Task)	Analyze bio-pharmaceuticals in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)
	Description	This NOS is about a Quality Control Biologist performing routine analysis in lab while ensuring compliance with Good Manufacturing Practices and Good Laboratory Practices
	Scope	The unit/ task covers the following <ul style="list-style-type: none"> • Perform quality Scheck • Conduct analysis& documentation in lab • Check upkeep of instruments
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Perform quality checks	To be competent, the user/individual on the job must be able to: <p>PC1. prepare the required buffer, solvent solutions and microbial media for running bio-analytical quality tests</p> <p>PC2. prepare and work on assays to carry out quality control procedures on biopharmaceutical products</p> <p>PC3. perform all the test activities and validations satisfactorily, including procedures such as cell culture, protein purifications etc.</p> <p>PC4. train the line staff effectively to perform tests</p> <p>PC5. manage manpower efficiently to undertake the needed tests</p> <p>PC6. ensure that all work meets applicable QA/QC guidelines</p> <p>PC7. review the data given by analysts and ensure that it is as per the SOP</p> <p>PC8. adhere to quality conformance standards and norms</p> <p>PC9. perform in vitro and in vivo potency tests on biologicals and biopharmaceuticals</p> <p>PC10. conduct studies involving animal handling and experimentation</p>
	Conduct analysis & documentation in lab	PC11. review and update test methods and procedures according to the SOP PC12. prepare reports to document findings and recommendations on time PC13. conduct all the analysis on time and as per the procedure PC14. coordinate effectively with personnel in other disciplines to integrate findings and recommendations PC15. identify causes for out-of-spec biopharmaceutical products and then recommend changes to improve the product's quality PC16. analyse root cause of deviations and take corrective actions PC17. participate in laboratory investigations when required PC18. fill log book, column, reagent, volumetric solution, working standard, reference standard entries, calibration records, etc. and evaluate assay performance, develop and implement assay optimization plans
	Check upkeep of instruments	PC19. conduct regular checks for proper positioning of all equipment and instrument tags PC20. conduct regular checks on equipment and instrument conditions and document calibrations

LFS/N0338 : Analyse bio-pharmaceuticals in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

	PC21. ensure precision in instrument calibrations to minimize source of errors
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	<p>The user/individual on the job needs to know and understand:</p> <ul style="list-style-type: none"> KA1. quality policy of the company KA2. good documentation practices of the company KA3. composition/requirements of the product manufactured KA4. standard operating procedures of the production unit KA5. legal and regulatory frameworks relevant to the production work and implications of failing to comply with those KA6. quality control methods approved by the company KA7. format of presenting the information captured during quality checks KA8. sample handling procedures used in the organization and what to do with a faulty sample
B. Technical Knowledge	<p>The user/individual on the job needs to know and understand:</p> <ul style="list-style-type: none"> KB1. all topics covered in the Lot Release Certification by the National Control Laboratory KB2. concepts of pharmacopeia like BP, USP, EP and other applicable guidelines such as WHO, ICH and EMEA, etc. KB3. statistical tools and software like combistats KB4. safe handling of infectious materials like cultures, strains and seed strains KB5. procedures for handling infectious spillage control KB6. market complaints and the investigation into adverse events following immunization (AEFI) KB7. good manufacturing practices, good weighing practices and good laboratory practices KB8. the WHO Technical Report Series and their recommendations on vaccines and the upgraded CTD requirements of CDSCO KB9. application of various biochemical analysis of proteins KB10. bio analytical and microbiological methods KB11. working of instruments/apparatus/equipment KB12. biological assays (i.e., ELISA, reporter-gene, receptor binding, etc.) , microorganisms etc. KB13. operation and cleaning procedure of various equipment used in QC KB14. application of various analytical techniques such as HPLC, capillary electrophoresis including icIEF, FTIR, Circular Dichroism, Field Flow Fractionation, UV and Fluorescence spectroscopy, ELISAs, enzyme assays and other applicable methods for the testing of biopharmaceuticals KB15. application of microbiological techniques such as air monitoring, water testing, surface monitoring, genus and species identification of various micro-organisms KB16. knowledge of biosafety levels and biosafety hazards

LFS/N0338 : Analyse bio-pharmaceuticals in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

	<p>KB17. working of stability chambers, autoclaves, BOD incubators, DT Apparatus, pH Meter, conductivity meter, digital balance, dissolution test apparatus, Karl Fischer apparatus, IR moisture balance, Polarimeter, digital Vernier calliper, TDS meter, refractometer, melting point apparatus, tapped density apparatus, friability test apparatus, TOC Analyser, potentiometric titrator, photoflurometer, antibiotic zone reader, colony counter, microscope, etc.</p> <p>KB18. working of complex equipment for invitro studies like - FACS Canto II Flow cytometer, PCR studies, Plate Reader, CO₂ Incubator, Fluostar Optima, Biological Safety Cabinets, ULT Freezer, Cooling Centrifuge and Tecan Sunrise Plate Reader</p> <p>KB19. animal handling techniques</p>
Skills (S)	
A. Core Skills/ Generic Skills	<p>Writing Skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. conduct documentation, including online documentation SA2. make legible entries with permanent ink SA3. write detailed reports for investigation SA4. pay attention to detail while recording production parameters</p> <p>Reading Skills</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA5. read important documents, reports and procedures accurately</p> <p>Oral Communication (Listening and Speaking skills)</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA6. interact with people to effectively gather information SA7. listen effectively and communicate information orally SA8. build and maintain positive and effective relationships with colleagues and customers</p>
B. Professional Skills	<p>Decision Making</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. analyse information and evaluate results to choose the best solution and solve problems SB2. use individual judgment to determine if test results or processes comply with regulations and standards SB3. make team decisions rather than individual decisions</p> <p>Plan and Organise</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB4. plan the work in a proper manner so that extensive load should not be there.</p>

LFS/N0338 : Analyse bio-pharmaceuticals in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

	SB5. plan work assigned on a daily basis and provide estimates of time required for each piece of work
	Problem Solving
	The user/individual on the job needs to know and understand how to:
	SB6. seek clarification on problems from others SB7. use effective problem solving techniques SB8. assess the problem
	Analytical Thinking
	The user/individual on the job needs to know and understand how to:
	SB9. analyse data and activities SB10. pass on relevant information to others
	Critical Thinking
	The user/individual on the job needs to know and understand how to:
	SB11. provide opinions on work in a detailed and constructive way SB12. apply balanced judgments to different approaches SB13. analyse the depth of issue and handle it with a proactive approach
Customer Centricity	
NA	

LFS/N0338 : Analyse bio-pharmaceuticals in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

NOS Version Control

NOS Code	LFS/N0338		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	22/12/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Quality	Next review date	01/08/19

LFS/N0101 : Maintain a healthy, safe and secure working environment in the Life Sciences Facility

National Occupational Standards



Overview

This Occupational Standard is about the knowledge, understanding and skills required by a Quality Control Biologist to ensure healthy, safe and secure working environment in the life sciences facility.

LFS/N0101 : Maintain a healthy, safe and secure working environment in the Life Sciences Facility

National Occupational Standard	Unit Code	LFS /N0101
	Unit Title (Task)	Maintain a healthy, safe and secure working environment in the life sciences facility
	Description	This NOS unit is about a Quality Control Biologist monitoring the working environment and making sure that it meets the requirements for health, safety and security in the pharmaceutical/contract research/biopharmaceutical facility/ manufacturing/ testing/ analysis/ research laboratory.
	Scope	<p>This unit / task covers the following:</p> <p>Ensuring healthy, safe and secure working environment:</p> <ul style="list-style-type: none"> • self monitor and adhere to safety principles and standards • ensure behavioural safety by workmen to cGMP and applicable safety standards on the shop floor/ laboratory • report any identified breaches in health, safety, and security policies and procedures to the designated person <p>Managing emergency procedures:</p> <ul style="list-style-type: none"> • illness • accidents • fires • other reasons to evacuate the premises • breaches of security
Performance Criteria (PC) wrt the Scope		
Element	Performance Criteria	
Ensuring healthy, safe and secure working environment	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. observe and comply with the company's current health, safety and security policies and procedures</p> <p>PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines</p> <p>PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person</p> <p>PC4. responsible for maintaining discipline at the shop-floor/ production area</p> <p>PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority</p> <p>PC6. adhere and comply to storage and handling guidelines for hazardous material</p> <p>PC7. identify and recommend opportunities for improving health, safety, and security to the designated person</p> <p>PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately</p>	
Managing emergency procedures	<p>PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected</p> <p>PC10. follow the company's emergency procedures promptly, calmly, and efficiently</p>	

LFS/N0101 : Maintain a healthy, safe and secure working environment in the Life Sciences Facility

Knowledge and Understanding (K)	
<p>A. Organisational Context (Knowledge of the Company/ Organisation and its processes)</p>	<p>The user/ individual on the job needs to know and understand:</p> <p>KA1. legislative requirements and company's procedures for health, safety and security and individual's role and responsibilities in relation to this</p> <p>KA2. what is meant by a hazard, including the different types of health and safety hazards that can be found in the workplace</p> <p>KA3. how and when to report hazards</p> <p>KA4. limits of individual responsibility for dealing with hazards</p> <p>KA5. the organization's emergency procedures for different emergency situations and the importance of following these</p> <p>KA6. the importance of maintaining high standards of health, safety and security</p> <p>KA7. implications that any non-compliance with health, safety and security may have on individuals and the organization</p> <p>KA8. health hazards and its implications if any in the production process</p>
<p>B Technical Knowledge</p>	<p>The user/ individual on the job needs to know and understand:</p> <p>KB1. different types of breaches in health, safety and security and how and when to report these</p> <p>KB2. evacuation procedures for workers and visitors</p> <p>KB3. how to summon medical assistance and the emergency services, where necessary</p> <p>KB4. how to use the health, safety and accident reporting procedures and the importance of these</p> <p>KB5. different types of occupational health hazards</p> <p>KB6. knowledge of chemical substances, their characteristics and required precaution and safety measures</p>
Skills (S)	
<p>A. Core Skills/ Generic Skills</p>	<p>Writing skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. complete accurate, well written work with attention to detail</p>
	<p>Reading skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA2. read instructions, guidelines, procedures, rules and service level agreements</p>
	<p>Oral Communication (Listening and Speaking skills)</p> <p>The user/ individual on the job needs to know and understand how to:</p>

LFS/N0101 : Maintain a healthy, safe and secure working environment in the Life Sciences Facility

	SA3. listen effectively and orally communicate information accurately
B. Professional Skills	Decision making
	The user/ individual on the job needs to know and understand how to:
	SB1. make decisions on suitable courses of action
	Plan and Organise
	The user/ individual on the job needs to know and understand how to:
	SB2. plan and organize work to meet health, safety and security requirements
	Problem solving
	The user/ individual on the job needs to know and understand how to:
	SB3. apply problem solving approaches in different situations
	Analytical thinking
	The user/ individual on the job needs to know and understand how to:
	SB4. analyse data and activities
Critical thinking	
The user/ individual on the job needs to know and understand how to:	
SB5. apply balanced judgments to different situations	
Customer Centricity	
NA	

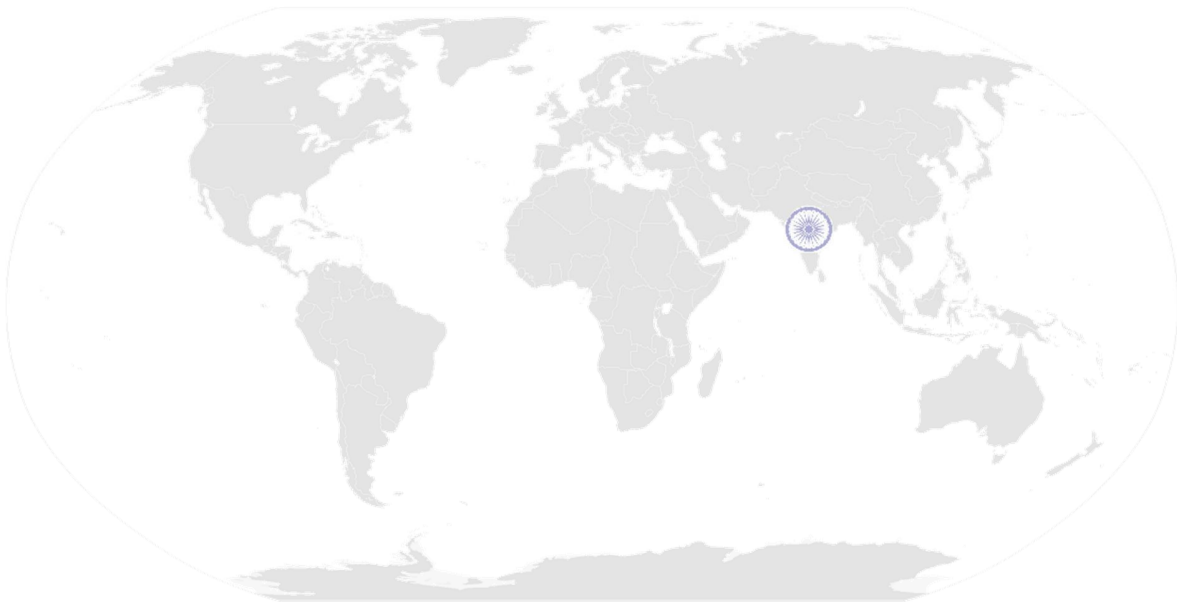
LFS/N0101 : Maintain a healthy, safe and secure working environment in the Life Sciences Facility
NOS Version Control

NOS Code	LFS/N0101		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	26/06/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/08/19



LFS/N0302 : Coordinate with Supervisors and colleagues within and outside the department

National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Biologist to work as a team member and multi-task in order to achieve production on schedule and meeting the quality requirements.

LFS/N0302 : Coordinate with Supervisors and colleagues within and outside the department

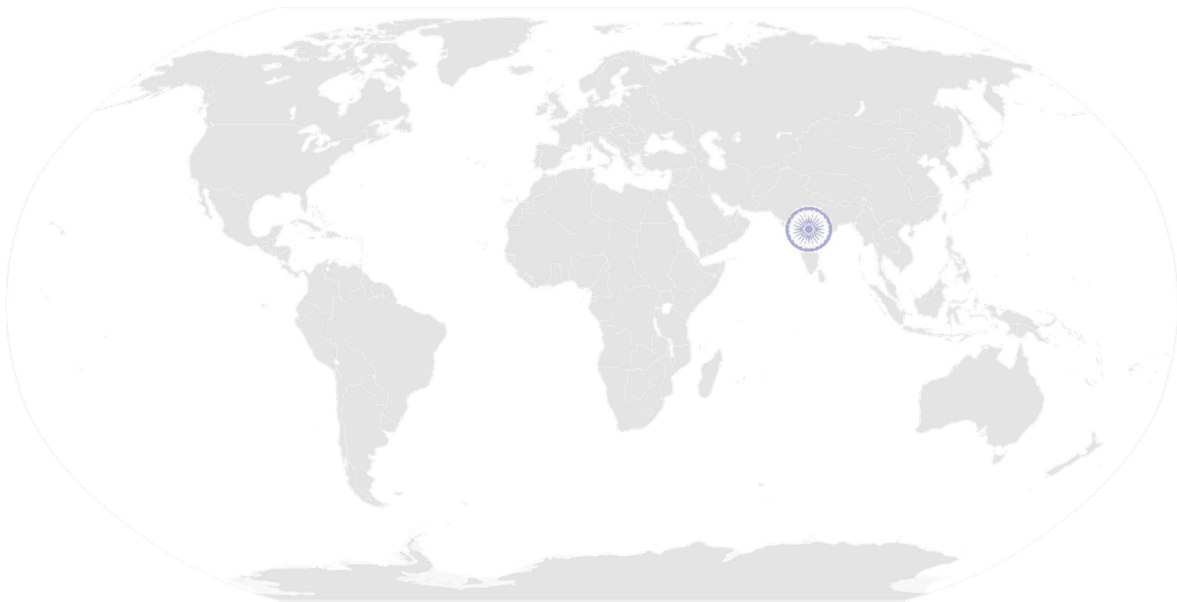
National Occupational Standard	Unit Code	LFS/N0302
	Unit Title (Task)	Coordinate with Supervisors and colleagues within and outside the department
	Description	This NOS unit is about the Quality Control Biologist coordinating with supervisors and colleagues within and outside the department
	Scope	The unit/ task covers the following: <ul style="list-style-type: none"> • Supervisors • Team management
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Coordination with Supervisor	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. receive work instructions from reporting supervisor PC2. communicate to reporting supervisor about process-flow improvements, production defects received from previous process, repairs and maintenance of equipment as required PC3. communicate deviations in the production process to reporting supervisor PC4. communicate any potential hazards or expected process disruptions PC5. handover completed work to supervisor
	Team Management	<ul style="list-style-type: none"> PC6. work as a team with colleagues and share work as per their or own work load and skills PC7. work and support colleagues of other departments PC8. train line or reporting staff if needed PC9. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement PC10. explain what information means and how it can be used to team members PC11. document all the control steps undertaken or recommended to be followed as per the standards
	Knowledge and Understanding (K)	
	A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> KA1. company's policies on: preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management KA2. reporting structure
B. Technical Knowledge	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> KB1. communicate effectively KB2. build team coordination 	

LFS/N0302 : Coordinate with Supervisors and colleagues within and outside the department

Skills (S)	
A. Core Skills/ Generic Skills	Writing skills
	The user/ individual on the job needs to know and understand how to: SA1. read job sheets and interpret technical details mentioned in the jobsheet
	Reading skills
	The user/individual on the job needs to know and understand how to: SA2. read notes/comments from the supervisor
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA3. interact with team members to work efficiently SA4. communicate with colleagues and supervisor to maintain an effective and smooth interpersonal relationship
B. Professional Skills	Decision Making
	The user/individual on the job needs to know and understand how to: SB1. spot and communicate potential areas of disruptions to work process and report the same SB2. when to report to supervisor and when to deal with a colleague individually, depending on the type of concern
	Critical Thinking
	The user/individual on the job needs to know and understand how to: SB3. spot process disruptions and delays and report and communicate with solutions SB4. improve work processes by interacting with others and adopting best practices
	Problem Solving
	NA
	Analytical Thinking
	NA
Plan and Organize	
NA	
Customer Centricity	
NA	

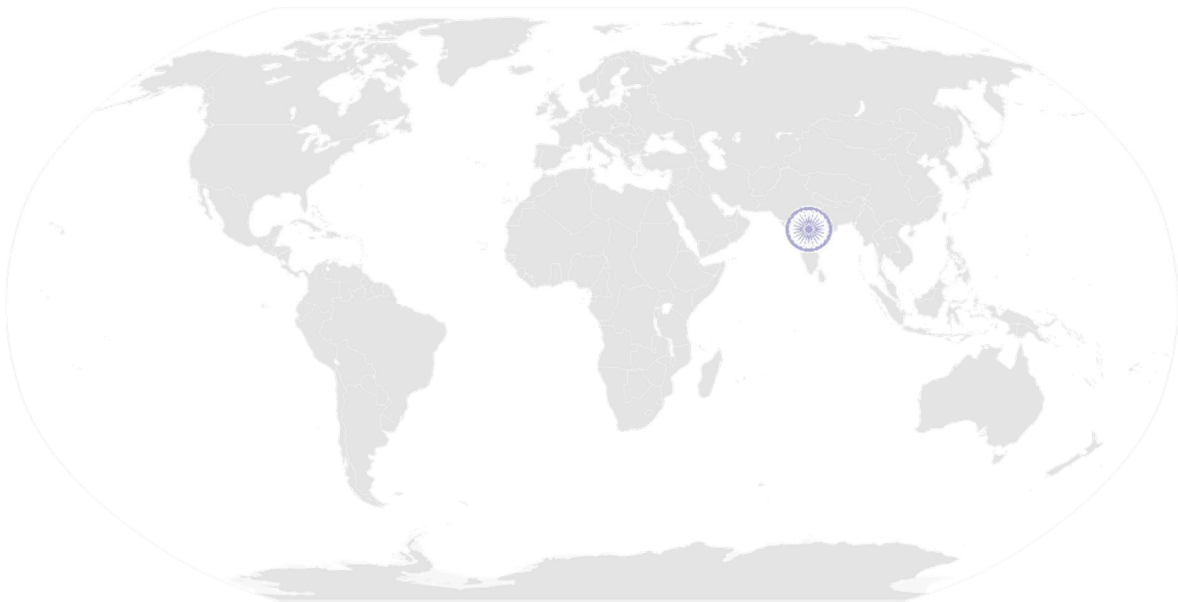
LFS/N0302 : Coordinate with Supervisors and colleagues within and outside the department
NOS Version Control

NOS Code	LFS/N0302		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	23/06/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Quality	Next review date	01/08/19



LFS/N0103 : Ensure cleanliness in the work area

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Biologist to ensure cleanliness in the work area by carrying out housekeeping for respective area

LFS/N0103 : Ensure cleanliness in the work area

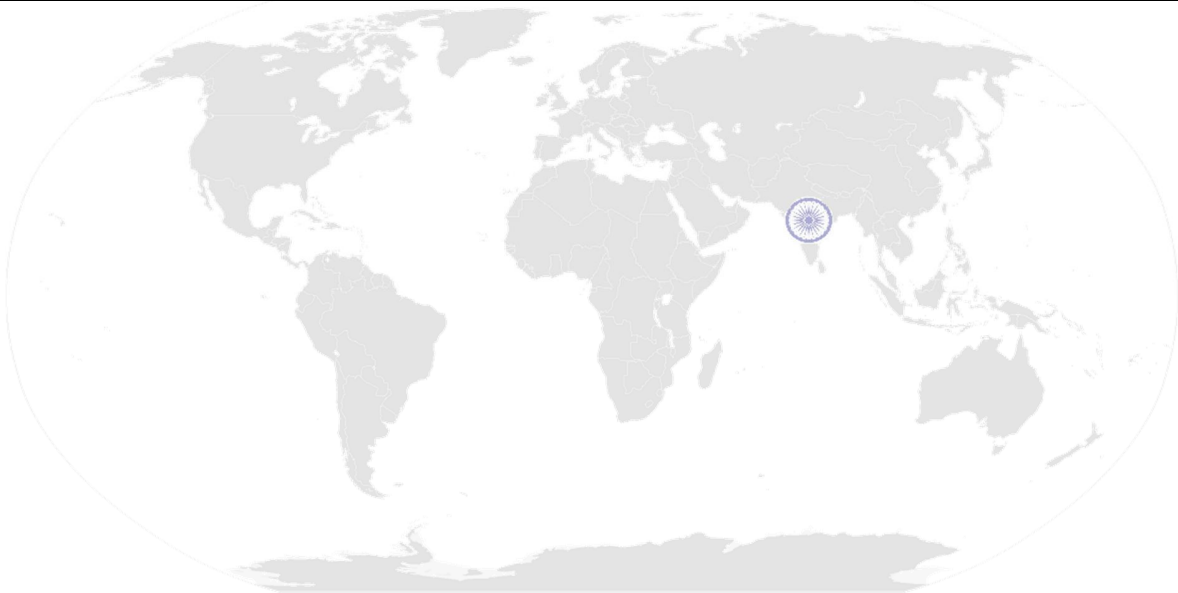
National Occupational Standard	Unit Code	LFS/N0103
	Unit Title (Task)	Ensure cleanliness in the work area
	Description	This NOS unit is about the Quality Control Biologist to carry out housekeeping activities for respective area
	Scope	This unit/task covers the following: <ul style="list-style-type: none"> • Pre housekeeping activities • Operations • Post housekeeping activities
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Pre housekeeping activities	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. inspect the area while taking into account various surfaces PC2. identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain PC3. ensure that the cleaning equipment is in proper working condition PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person PC5. plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces PC6. inform the affected people about the cleaning activity PC7. display the appropriate signage for the work being conducted PC8. ensure that there is adequate ventilation for the work being carried out PC9. wear the personal protective equipment required for the cleaning method and materials being used
	Operations	<ul style="list-style-type: none"> PC10. use the correct cleaning method for the work area, type of soiling and surface PC11. deal with accidental damage, if any, caused while carrying out the work PC12. report to the appropriate person any difficulties in carrying out work PC13. identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill
	Post housekeeping activities	<ul style="list-style-type: none"> PC14. ensure that there is no oily substance on the floor to avoid slippage PC15. ensure that no scrap material is lying around PC16. maintain and store housekeeping equipment and supplies PC17. follow workplace procedures to deal with any accidental damage caused during the cleaning process PC18. ensure that, on completion of the work, the area is left clean and dry and meets requirements

LFS/N0103 : Ensure cleanliness in the work area

	<p>PC19. return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored</p> <p>PC20. dispose the waste garnered from the activity in an appropriate manner</p> <p>PC21. dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly</p> <p>PC22. maintain schedules and records for housekeeping duty</p> <p>PC23. replenish any necessary supplies or consumables</p>
Knowledge and Understanding (K)	
<p>A. Organisational Context (Knowledge of the Company/ Organisation and its processes)</p>	<p>The user/individual on the job needs to know and understand:</p> <p>KA1. levels of hygiene required by storage area and importance of maintaining the same</p> <p>KA2. methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment</p> <p>KA3. the method to check the treated surface and equipment on completion of cleaning</p> <p>KA4. procedures for reporting any unidentified soiling</p> <p>KA5. escalation procedures for soils or stains that could not be removed</p>
<p>B. Technical Knowledge</p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. role of different materials, chemicals and equipment</p>
Skills (S)	
<p>A. Core Skills/ Generic Skills</p>	<p>Writing Skills</p>
	<p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail</p>
	<p>Reading and Understanding Skills</p>
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SA2. understand the various coding systems as per company norms</p>
	<p>Oral Communication (Listening and Speaking skills)</p>
<p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. communicate with upstream and downstream teams</p> <p>SA4. disclose information only to those who have the right and need to know it.</p>	
	<p>Critical Thinking</p>

LFS/N0103 : Ensure cleanliness in the work area

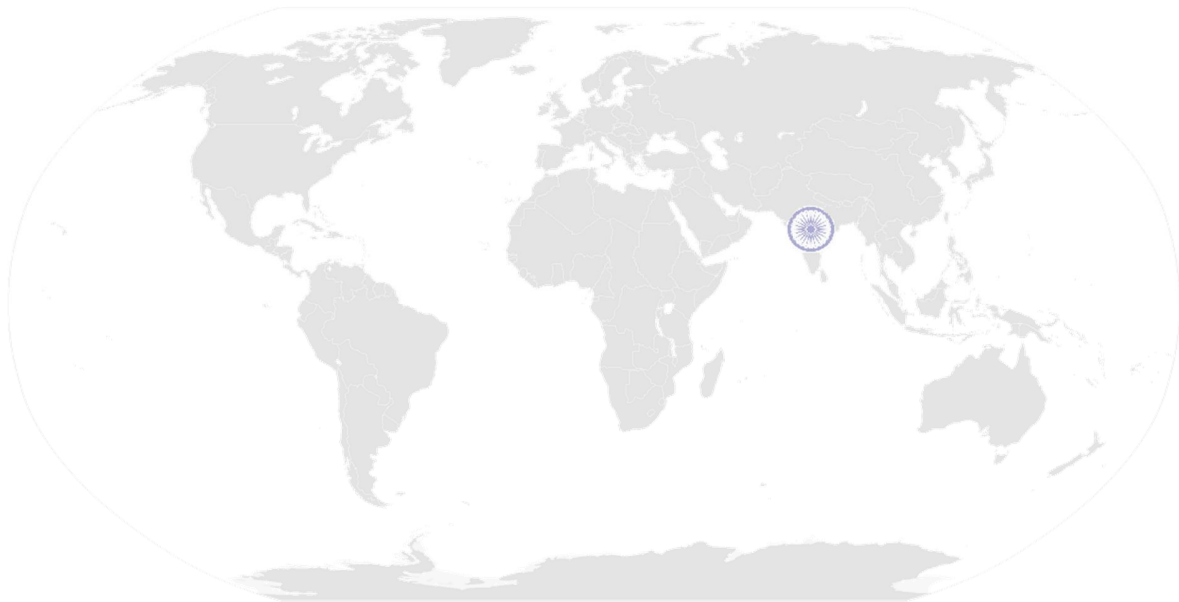
B. Professional Skills	The user/individual on the job needs to know and understand how to:
	SB1. suggest improvements(if any) in process based on experience
	Decision Making
	SB2. make decisions to maintain cleanliness in the area of work
	Analytical Thinking
	NA
	Problem Solving
	NA
	Plan and Organize
	NA
Customer Centricity	
NA	



LFS/N0103 : Ensure cleanliness in the work area

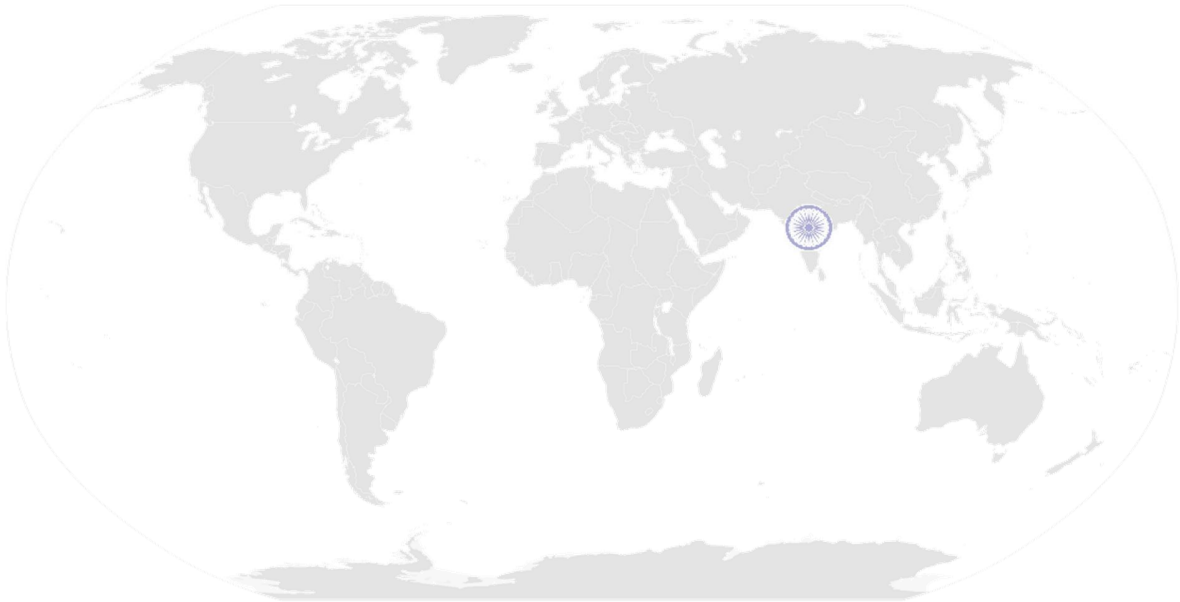
NOS Version Control

NOS Code	LFS/N0103		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	22/12/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/08/19



LFS/N0314 : Carry out reporting and documentation to meet quality standards

National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Biologist to carry out reporting and documentation to meet quality standards

LFS/N0314 : Carry out reporting and documentation to meet quality standards

National Occupational Standard	Unit Code	LFS/N0314
	Unit Title (Task)	Carry out reporting and documentation to meet quality standards
	Description	This NOS unit is about the Quality Control Biologist carrying out reporting and documentation to meet quality standards and ensure that the final documents meet regulatory and compliance requirements
	Scope	The unit/ task covers the following: <ul style="list-style-type: none"> • Reporting of defects/problem/incidents/quality issues/test results • Recording and Documentation • Information Security
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Reporting	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. report defects/problem/incidents/quality issues/test results as applicable in a timely manner PC2. report to the appropriate authority as laid down by the company PC3. follow reporting procedures as prescribed by the company PC4. work with production management and quality assurance to provide feedback regarding quality standards and issues PC5. help other R&D lab staff with any other testing required during the developmental work
	Recording and documentation	<ul style="list-style-type: none"> PC6. identify documentation to be completed relating to one's role PC7. record details accurately in appropriate format using offline and online mode depending on SOP guidelines PC8. accurately document the results of the inspections and testing PC9. maintain all controlled document files and test records in a timely and accurate manner PC10. ensure that the final document meets regulatory and compliance requirements PC11. make sure documents are available to all appropriate authorities to inspect PC12. evaluate problems and make initial recommendations for possible corrective action to supervise PC13. perform review of records and other documentation for compliance to established procedures and good documentation practices PC14. write and update the inspection procedures, protocols and checklists PC15. prepare inspection reports as per the inspection activity performed

LFS/N0314 : Carry out reporting and documentation to meet quality standards

Information Security	PC16. respond to requests for information in an appropriate manner whilst following organizational procedures PC17. inform the appropriate authority of requests for information received
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA1. procedures for reporting any unresolved issues and hazards KA2. reporting incidents where standard operating procedures are not followed KA6. the importance of complete and accurate documentation KA7. proper procedure for selecting the material/product and performing quality checks without affecting the material KA8. characteristics of the product/material KA9. availability and use of monitoring and measuring devices
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. high-end knowledge of quality control laboratory tools like photofluorometer, gas chromatography, HPCL, pH meter, etc. KB2. inspection or test points (control points) in the process and the related procedures and recording requirements KB3. common causes of variation and corrective action required KB4. operational health and safety (OHS) hazards and controls, including limitations of protective clothing and equipment relevant to the work process KB5. procedures and responsibility for reporting production and performance information
Skills (S)	
A. Core Skills/ Generic Skills	Writing Skills
	The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA2. maintain proper and concise records as per given format
	Reading Skills
	The user/individual on the job needs to know and understand how to: SA3. read notes/comments from supervisors and stakeholders SA4. disclose information only to those who have the right and need to know it SA5. communicate confidential and sensitive information discretely to authorized person as per SOP
	Oral Communication (Listening and Speaking skills)

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	The user/individual on the job needs to know and understand how to: SA6. communicate effectively with the team members and supervisors
B. Professional Skills	Decision Making
	The user/individual on the job needs to know and understand how to: SB1. decide whether the quality standards are been met or not
	Plan and Organise
	The user/individual on the job needs to know and understand how to: SB2. plan the quality research work within timeline and budget SB3. planning skills with the ability to multi-task and adapt
	Critical Thinking
	The user/individual on the job needs to know and understand how to: SB4. suggest improvements(if any) in process based on experience
	Problem Solving
	The user/individual on the job needs to know and understand how to: SB5. effectively solve problems while organizing SB6. think through problems, evaluate the possible solution(s) and suggest an optimum /best possible solution(s) SB7. identify immediate or temporary solutions to resolve delays
	Analytical Thinking
	The user/individual on the job needs to know and understand how to: SB8. use of computer/ application software SB9. attention to detail SB10. arithmetic and mechanical aptitude to resolve issues
	Customer Centricity
	NA

LFS/N0314 : Carry out reporting and documentation to meet quality standards

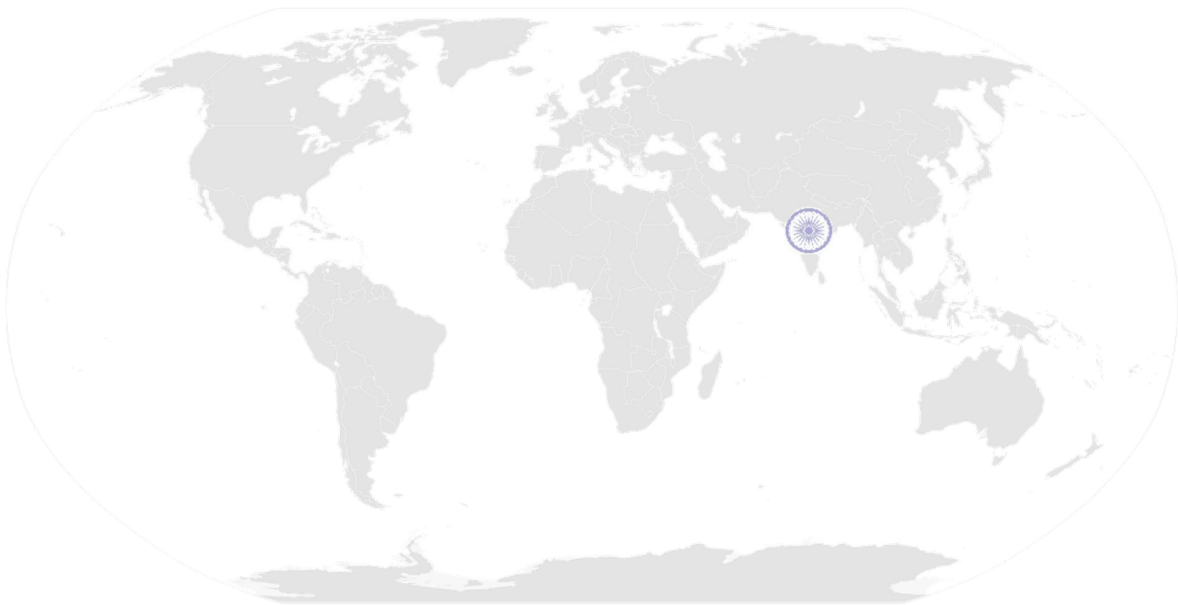
NOS Version Control

NOS Code	LFS/N0314		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	22/12/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Quality	Next review date	01/08/19



LFS/N0320 : Carry out quality checks in the quality control process

National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Quality Control Biologist to carry out quality checks in the quality control process.

LFS/N0320 : Carry out quality checks in the quality control process

National Occupational Standard	Unit Code	LFS/N0320
	Unit Title (Task)	Carry out quality checks in the quality control process
	Description	This NOS unit is about the Quality Control Biologist carrying out quality checks in the quality control process
	Scope	The unit/ task covers the following: <ul style="list-style-type: none"> Carrying out quality checks to identify problems in inspection Analysis
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Inspection	To be competent, the user/individual on the job must be able to: <p>PC1. ensure that total range of checks are regularly and consistently performed</p> <p>PC2. use appropriate measuring instruments, equipment, tools, accessories etc. ,as required</p> <p>PC3. ensure the status and accuracy of instruments used for measurement</p>
	Analysis	PC4. identify non-conformities to quality assurance standards PC5. identify potential causes of non-conformities to quality assurance standards PC6. identify impact on final product due to non-conformance to company standards PC7. evaluating the need for action to ensure that problems do not recur PC8. suggest corrective action to address problem PC9. review effectiveness of corrective action
	Knowledge and Understanding (K)	
	A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <p>KA1. the method to check the treated surface and equipment on completion of cleaning</p> <p>KA2. procedures for reporting any unidentified soiling</p> <p>KA3. escalation procedures for soils or stains that could not be removed</p> <p>KA4. reporting incidents where standard operating procedures are not followed</p> <p>KA5. the importance of complete and accurate documentation</p> <p>KA6. the importance of quality control procedures</p> <p>KA7. proper procedure for selecting the material/product and performing quality checks without affecting the material</p> <p>KA8. characteristics of the product/material</p> <p>KA9. availability and use of monitoring and measuring devices</p> <p>KA10. implications of inaccurate measuring and testing instruments and equipment</p>

LFS/N0320 : Carry out quality checks in the quality control process

<p>B. Technical Knowledge</p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. importance of maintaining master sample</p> <p>KB2. statistical analysis of test data, techniques and concepts of statistical quality control and statistical process control</p> <p>KB3. knowledge pertaining to functioning of quality control equipment like stability chambers and BOD incubators</p> <p>KB4. high-end operational knowledge of quality lab tools like HPLC, gas chromatography, photofluorometer, etc.</p>
<p>Skills (S)</p>	
<p>A .Core Skills/ Generic Skills</p>	<p>Writing Skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail</p> <p>SA2. maintain proper and concise records as per given format</p> <p>Reading Skills</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA3. read images, graphs, diagrams</p> <p>SA4. understand the various coding systems as per company norms</p> <p>Oral Communication (Listening and Speaking skills)</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SA5. communicate effectively with the team members and supervisors</p>
<p>B. Professional Skills</p>	<p>Decision Making</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. decide whether the quality standards are been met or not and take decisions appropriately</p> <p>Plan and Organise</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB2. plan the quality research work within timeline and budget</p> <p>SB3. ensure timelines are met and delegate tasks as per individual competencies</p> <p>Analytical Thinking</p> <p>The user/individual on the job needs to know and understand how to:</p> <p>SB4. use of computer/ application software</p> <p>SB5. attention to detail</p> <p>Problem Solving</p>

LFS/N0320 : Carry out quality checks in the quality control process

	The user/individual on the job needs to know and understand how to:
	SB6. effectively solve problems while organizing
	SB7. think through problems, evaluate the possible solution(s) and suggest an optimum /best possible solution(s)
	SB8. identify immediate or temporary solutions to resolve delays
	Critical Thinking
	The user/individual on the job needs to know and understand how to:
	SB9. suggest improvements(if any) in process based on experience
	Customer Centricity
	NA



LFS/N0320 : Carry out quality checks in the quality control process

NOS Version Control

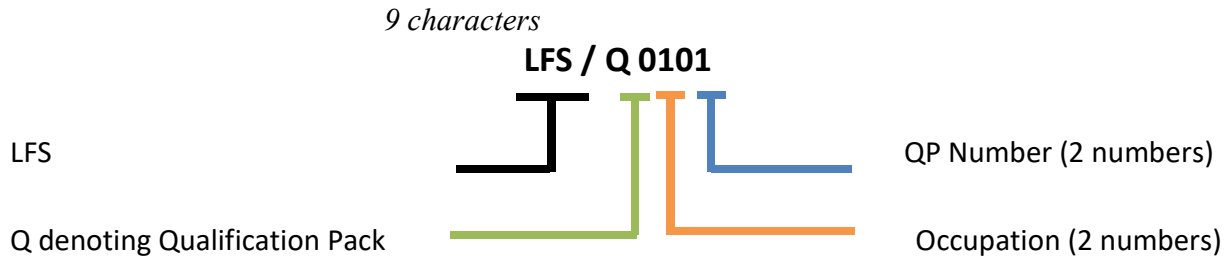
NOS Code	LFS/N0320		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	22/12/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Quality	Next review date	01/08/19



Qualifications Pack for Quality Control Biologist
Annexure

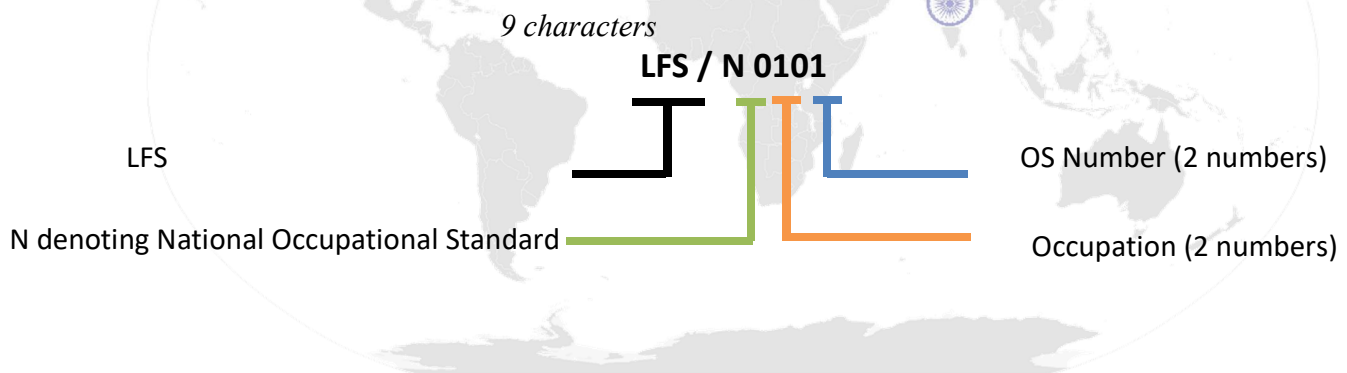
Nomenclature for QP and NOS

Qualification Pack



Occupational Standard

An example of NOS with 'N'



Qualifications Pack for Quality Control Biologist

The following acronyms/codes have been used in the nomenclature above:

Sub-Sector	Range of Occupation Numbers
Pharmaceutical and Biopharmaceutical and Contract Research	01-10
Pharmaceutical	11-20
Biopharmaceutical	21-30
Contract Research	31-40

Sequence	Description	Example
Three letters	Industry name	LFS
Slash	/	/
Next letter	Whether QP or NOS	Q/N
Next two numbers	Occupation code	01
Next two numbers	OS number	01

Qualifications Pack for Quality Control Biologist
CRITERIA FOR ASSESSMENT OF TRAINEES

Job Role Quality Control Biologist
Qualification Pack LFS/Q2301
Sector Skill Council Life Sciences Sector Skill Development Council

Guidelines for Assessment:

1. Criteria for assessment for each Qualification Pack will be created by the Sector Skill Council. Each Performance Criteria (PC) will be assigned marks proportional to its importance in NOS. SSC will also lay down proportion of marks for Theory and Skills Practical for each PC.
2. The assessment for the theory part will be based on knowledge bank of questions created by the SSC.
3. Individual assessment agencies will create *unique question papers for theory part for each candidate at each examination/training center* (as per assessment criteria below)
4. Individual assessment agencies will create *unique evaluations for skill practical for every student at each examination/training center* based on this criteria
5. To pass the Qualification Pack, every trainee should score a minimum of 70% in every NOS
6. In case of successfully passing only certain number of NOS's, the trainee is eligible to take subsequent assessment on the balance NOS's to pass the Qualification Pack.

Assessment Outcome	Assessment Criteria of Outcomes	Total Marks (600)	Out Of	Marks Allocation	
				Theory	Skills Practical
LFS/N0338 (Analyse bio pharmaceutical in lab while ensuring compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP))	PC1. prepare the required buffer, solvent solutions and microbial media for running bio-analytical quality tests	100	3	1	2
	PC2. prepare and work on assays to carry out quality control procedures on biopharmaceutical products		6	3	3
	PC3. perform all the test activities and validations satisfactorily, including procedures such as cell culture, protein purifications etc.		5	2	3
	PC4. train the line staff effectively to perform tests		6	3	3
	PC5. manage manpower efficiently to undertake the needed tests		6	3	3
	PC6. ensure that all work meets applicable QA/QC guidelines		6	3	3
	PC7. review the data given by analysts and ensure that it is as per the SOP		6	3	3

Qualifications Pack for Quality Control Biologist

PC8. adhere to quality conformance standards and norms	6	3	3
PC9. perform in vitro and in vivo potency tests on biologicals and biopharmaceuticals	4	2	2
PC10. review and update test methods and procedures according to the SOP	4	2	2
PC11. prepare reports to document findings and recommendations on time	4	2	2
PC12. conduct all the analysis on time and as per the procedure	6	2	4
PC13. coordinate effectively with personnel in other disciplines to integrate findings and recommendations	4	2	2
PC14. identify causes for out-of-spec biopharmaceutical products and then recommend changes to improve the product's quality	4	2	2
PC15. analyse root cause of deviations and take corrective actions	4	2	2
PC16. participate in laboratory investigations when required	4	1	3
PC17. fill log book, column, reagent, volumetric solution, working standard, reference standard entries, calibration records, etc. and evaluate assay performance, develop and implement assay optimization plans	4	2	2
PC18. evaluate assay performance, develop and implement assay optimization plans	2	1	1
PC19. conduct regular checks for proper positioning of all equipment and instrument tags	4	2	2

Qualifications Pack for Quality Control Biologist

	PC20. conduct regular checks on equipment and instrument conditions and document calibrations		4	2	2
	PC21. ensure precision in instrument calibrations to minimize source of errors		4	2	2
	PC22. conduct studies involving animal handling and experimentation		4	2	2
	Total		100	47	53
LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility)	PC1. observe and comply with the company's current health, safety and security policies and procedures	100	10	5	5
	PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		10	5	5
	PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person		10	5	5
	PC4. responsible for maintaining discipline at the shop-floor/ production area		10	5	5
	PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority		10	5	5
	PC6. adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. complete any health, safety and security records legibly and accurately		10	4	6
	PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational		10	4	6

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	procedures and warn other people who may be affected				
	PC10. follow the company's emergency procedures promptly, calmly, and efficiently		10	5	5
	Total		100	48	52
LFS/N0302 (Coordinate with Supervisors and colleagues within and outside the department)	PC1. receive work instructions from reporting supervisor	100	10	5	5
	PC2. communicate to reporting supervisor about process-flow improvements, production defects received from previous process, repairs and maintenance of equipment as required		10	5	5
	PC3. communicate deviations in the production process to reporting supervisor		10	5	5
	PC4. communicate any potential hazards or expected process disruptions		10	4	6
	PC5. handover completed work to supervisor		10	5	5
	PC6. work as a team with colleagues and share work as per their or own work load and skills		10	5	5
	PC7. work and support colleagues of other departments		6	3	3
	PC8. train line or reporting staff if needed		8	3	5
	PC9. communicate and discuss work flow related difficulties in order to find solutions with mutual agreement		7	3	4
	PC10. explain what information means and how it can be used to team members		9	4	5
	PC11. document all the control steps undertaken or recommended to be followed as per the standards		10	4	6
	Total		100	46	54
LFS/N0320 (Carry out quality checks in the quality control process)	PC1. ensure that total range of checks are regularly and consistently performed	100	16	8	8
	PC2. use appropriate measuring instruments, equipment, tools, accessories etc. ,as required		13	5	8

Qualifications Pack for Quality Control Biologist

	PC3. ensure the status and accuracy of instruments used for measurement		10	5	5
	PC4. identify non-conformities to quality assurance standards		13	5	8
	PC5. identify potential causes of non-conformities to quality assurance standards		13	5	8
	PC6. identify impact on final product due to non-conformance to company standards		16	8	8
	PC7. evaluating the need for action to ensure that problems do not recur		6	3	3
	PC8.suggest corrective action to address problem		7	3	4
	PC9.review effectiveness of corrective action		6	3	3
	Total		100	45	55
LFS/N0314 (Carry out reporting and documentation to meet quality standards)	PC1. report defects/problem/incidents/quality issues/test results as applicable in a timely manner	100	10	5	5
	PC2.report to the appropriate authority as laid down by the company		3	1	2
	PC3.follow reporting procedures as prescribed by the company		4	2	2
	PC4.work with production management and quality assurance to provide feedback regarding quality standards and issues		4	2	2
	PC5.help other R&D lab staff with any other testing required during the developmental work		4	2	2
	PC6.identify documentation to be completed relating to one's role		7	3	4
	PC7.record details accurately in appropriate format using offline and online mode depending on SOP guidelines		6	3	3
	PC8.accurately document the results of the inspections and testing		8	4	4

Qualifications Pack for Quality Control Biologist

	PC9.maintain all controlled document files and test records in a timely and accurate manner		10	5	5
	PC10.ensure that the final document meets regulatory and compliance requirements		7	2	5
	PC11.make sure documents are available to all appropriate authorities to inspect		5	2	3
	PC12.evaluate problems and make initial recommendations for possible corrective action to supervise		4	2	2
	PC13.perform review of records and other documentation for compliance to established procedures and good documentation practices		8	4	4
	PC14.write and update the inspection procedures, protocols and checklists		6	2	4
	PC15.prepare inspection reports as per the inspection activity performed		6	2	4
	PC16.respond to requests for information in an appropriate manner whilst following organizational procedures		4	2	2
	PC17.inform the appropriate authority of requests for information received		4	2	2
	Total		100	45	55
LFS/N0103 (Ensure cleanliness in the work area)	PC1.inspect the area while taking into account various surfaces	100	4	2	2
	PC2.identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain		5	2	3
	PC3.ensure that the cleaning equipment is in proper working condition		5	2	3
	PC4.select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not		4	2	2

Qualifications Pack for Quality Control Biologist

available and inform the appropriate person			
PC5.plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces	4	1	3
PC6.inform the affected people about the cleaning activity	4	2	2
PC7.display the appropriate signage for the work being conducted	4	2	2
PC8.ensure that there is adequate ventilation for the work being carried out	5	2	3
PC9.wear the personal protective equipment required for the cleaning method and materials being used	4	2	2
PC10.use the correct cleaning method for the work area, type of soiling and surface	4	2	2
PC11.deal with accidental damage, if any, caused while carrying out the work	4	1	3
PC12.report to the appropriate person any difficulties in carrying out your work	4	2	2
PC13.identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill	4	2	2
PC14.ensure that there is no oily substance on the floor to avoid slippage	4	2	2
PC15.ensure that no scrap material is lying around	4	2	2
PC16.maintain and store housekeeping equipment and supplies	4	2	2
PC17.follow workplace procedures to deal with any accidental damage caused during the cleaning process	4	2	2
PC18.ensure that, on completion of the work, the area is left clean and dry and meets requirements	4	2	2

Qualifications Pack for Quality Control Biologist

	PC19.return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored		5	2	3
	PC20.dispose the waste garnered from the activity in an appropriate manner		5	2	3
	PC21.dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly		5	2	3
	PC22.maintain schedules and records for housekeeping duty		5	2	3
	PC23.replenish any necessary supplies or consumables		5	2	3
		Total	100	44	56
				100	